

**IN THE CLAIMS:**

1. (currently amended) A prosthesis for protecting a part of a human body from developing a pressure ulcer or for healing an existing pressure ulcer, where the body part includes a bone structure and a soft tissue layer between the bone structure and an outer skin layer intended to be in contact with a support structure, comprising:

a protective device to be applied to the body part to be protected; said protective device having an inner surface conforming to the body part to which it is applied and having an outer surface suitable for making contact with the support structure; and said protective device having sufficient thickness and softness to distribute the weight of the body part over an extended area and volume to reduce the pressure exerted at the interface between the bone structure and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding outer skin layer and between the corresponding outer skin layer and the support structure; and

wherein the bone structure of the body part to be protected includes a bony prominence tending to concentrate the weight of the body part over a small region tending to increase the pressure at the interface between the bony prominence and its corresponding soft tissue layer, and wherein the protective device is shaped to enclose the portion of the body part containing the bony prominence and the bony prominence and the protective device being shaped to extend continuously between the body part and the bony prominence containing

the bony prominence and the support structure to increase the effective surface area and volume over which the concentrated weight at the bony prominence is distributed in the space between the bony prominence and the support surface in order to reduce the pressure developed at the interface between the bony prominence and its corresponding soft tissue layer to a level which is less than the pressure that would cause a pressure ulcer to develop in that part of the body.

- 2: (currently amended) The prosthesis as claimed in claim 1, wherein the ~~bone structure includes a bony prominence tending to concentrate the weight of the body part over a small region tending to increase the pressure at the interface between the bony prominence and its corresponding soft tissue layer, and wherein the protective device is shaped to reduce the pressure developed at the interface between the bony prominence and its corresponding soft tissue layer for reducing the pressure that would cause a pressure ulcer to develop in that part of the body~~ concentrated weight at the bony prominence due to the bone structure and its corresponding overlying body part is defined as **W** and wherein, when the body part is in direct contact with the support surface, the weight **W** is distributed over a small area, defined as **X**, at the interface between the bony prominence and its corresponding soft tissue layer resulting in a pressure  $P_1$  equal to  $W/X$  at the interface between the bony prominence and its underlying soft tissue layer; and wherein the protective device enclosing the body part containing the bony prominence, located

between the body part and the support surface, causes the effective area between the bony prominence and its associated soft tissue layer over which the weight W is distributed to be equal to Y, where Y is greater than X, whereby the resulting pressure between the bony prominence and its underlying soft tissue layer is equal to P2, which is equal to  $W/Y$ , where P2 is less than P1, and P2 is less than a critical value of pressure which would tend to cause ulcers in the body part.

3. (currently amended) The prosthesis as claimed in claim 2 1 wherein the protective device is shaped to increase the area over which the weight at the bony prominence is distributed as a function of the distance from the bony prominence to the support surface.

4. (currently amended) The prosthesis as claimed in claim 2 1 wherein the protective device conforms to the body part to which it is applied and is shaped for causing the weight concentrated at the bony prominence to be distributed over a larger area at the interface between the bony prominence and the soft tissue layer and over an area and volume which increases as the distance from the bony prominence to the support surface increases; and

wherein the body part on which the protective device is mounted can be freely moved in any direction.

5. (currently amended) The prosthesis as claimed in claim 2 4 wherein the thickness of the protective device may be selectively increased to decrease the pressure at the interface between the bony prominence and the corresponding soft tissue layer .

6. (currently amended) The prosthesis as claimed in claim 1 wherein the protective device ~~is~~ includes a ~~pad-like structure~~ and wherein the thickness of the ~~pad-like structure~~ may be selectively increased by adding layers to its outer surface.

7. (original) The prosthesis as claimed in claim 1, wherein the body part to be protected is at least one of the heel, ankle, trochanter, knee, sacrum, coccyx, buttocks, ischium, scapula, elbow and occiput; and wherein the inner surface of the protective device conforms to its respective body part.

8. (original) The prosthesis as claimed in claim 7, wherein the outer surface of the protective device includes a hard outer shell.

9. (original) The prosthesis as claimed in claim 7, wherein the outer surface of the protective device includes a hard outer shell for insulating the body part from the effects of the support structure.

10. (original) The prosthesis as claimed in claim 9, wherein the inner surface of the protective device also includes a hard inner shell.

11. (currently amended) The prosthesis as claimed in claim 3, wherein the protective device ~~is~~ includes a ~~pad-like structure~~ which is made of a soft material having sufficient thickness to reduce the pressures developed within the body part to enable the body part to which the ~~pad-like structure~~ is applied to rest on the support structure for an extended period of time without developing a pressure ulcer.

12. (currently amended) The prosthesis as claimed in claim 11, wherein the portion of the outer surface of the ~~pad-like structure~~ making contact with the support structure conforms generally to the shape of the support structure.
13. (currently amended) The prosthesis as claimed in claim ~~2~~ 4 wherein the protective device is includes a ~~pad-like structure~~ and the inner surface of the ~~pad-like structure~~ conforms to the shape of a heel and extends from the arch to above the ankle.
14. (currently amended) The prosthesis as claimed in claim 13, wherein the ~~pad like structure~~ is fitted to be worn by a user and to cover an area ranging from the arch to at least the ankle of a user.
15. (currently amended) The prosthesis as claimed in claim 13, wherein the portion of the ~~pad-like structure~~ extending beneath the foot and the heel extends the full width of the foot and the heel and is generally of cylindrical shape.
16. (currently amended) The prosthesis as claimed in claim 13, wherein the ~~pad-like structure~~ is shaped like a semi-cylindrical sleeve located behind the ankle and leg and extending from below the foot to above the ankle.
17. (currently amended) The prosthesis as claimed in claim 13, wherein the inner portion of the ~~pad-like structure~~ extends around the bottom portion of the foot and ankle region and a portion of its shape may be one of the following: rectangular, cylindrical, semi-cylindrical, toroidal, ellipsoid, oblong, triangular and a combination thereof.
18. (original) The prosthesis as claimed in claim 7, wherein each protective device includes means for securing the device to its corresponding body part.

19. (original) The prosthesis as claimed in claim 3 wherein each protective device is placed around its corresponding body part so as to protect the body part regardless of the orientation of the body part on, or off, the support structure.

20. (currently amended) The prosthesis as claimed in claim 2, 4 wherein the protective device is shaped to redistribute weight from the area of the bony prominence to other portions of the body part.

21. (original) The prosthesis as claimed in claim 1, wherein there is included between the outer skin layer and the inner surface of the protective device at least one of the following:

- (a) a layer of dressing;
- (b) a layer of medicated dressing;
- (c) a layer of hydrocolloid dressing;
- (d) a layer of hydrocolloid dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- (e) a layer of hydrogel;
- (f) a layer of hydrogel dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- (g) a thin film dressing;
- (h) a thin film dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;

- (i) a layer of gauze dressing;
- (j) a layer of gauze dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- (k) a layer of non woven-dressing;
- (l) a layer of non woven-dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- (m) a layer of foam dressing;
- (n) a layer of foam dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- (o) a layer of material adapted to absorb any excess moisture and drainage;
- (p) a layer of material which exhibits moisture vapor permeability for removal of excess moisture; and
- (q) a layer of material which exhibits permeability to air for enabling air circulation for removing excess heat and moisture; and
- (r) a layer of material containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance.

22. (original) The prosthesis as claimed in claim 1, wherein the protective device includes at least one of the following:

- (s) a dressing;
- (t) a medicated dressing;
- (u) a hydrocolloid dressing;
- (v) a hydrocolloid dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- (w) a hydrogel;
- (x) a hydrogel dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- (y) a thin film dressing;
- (z) a thin film dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- (aa) a gauze dressing;
- (bb) a gauze dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- (cc) a non woven-dressing;
- (dd) a non woven-dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- (ee) a foam dressing;



- (ff) a foam dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- (gg) a material adapted to absorb any excess moisture and drainage;
- (hh) a material which exhibits moisture vapor permeability for removal of excess moisture; and
- (ii) a material which exhibits permeability to air for enabling air circulation; and
- (jj) a material containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance.

23. (original) The prosthesis as claimed in claim 3 wherein the support structure may be one of: a horizontal surface having a wide range of firmness on which a human body is to rest, a mattress having a wide range of firmness, a seating structure, and any prosthetic used to replace a body part.

24. (currently amended) A prosthesis for protecting a part of a human body from developing a pressure ulcer or for healing an existing pressure ulcer, where the body part includes a bony portion surrounded by a soft tissue layer between the bony portion and an outer skin layer and wherein, when the body part is in contact with a support surface, wherein the bony portion tends to concentrate the

weight of the part within a relative small region defining a pressure cone, and the weight of the body part including the bony portion may tending to cause a pressure gradient to be developed at the interface between the bony portion and the soft tissue layer, across the soft tissue layer and between the skin layer and the support surface and may cause a pressure ulcer to develop in the body part, where the pressure at any point is a function of the weight applied at a point divided by the area over which the weight is distributed, the prosthesis comprising:

a protective device to be applied to the body part to be protected and placed between the body part containing the bony portion and the support surface; said protective device having an inner surface conforming to the body part to which it is applied and having an outer surface suitable for making contact with the support surface; and said protective device extending continuously from the region of the body part containing the bony portion to the support surface and shaped for increasing the effective area and volume over which the concentrated weight present at the interface between the bony portion and its surrounding soft tissue layer is distributed and for distributing the weight of the body part and of the bony portion over ~~an extended~~ the increased effective area and volume ~~for effectively increasing the area and volume of the pressure cone~~ and thereby reducing the pressure due to the bony point exerted at the interface between the bony portion and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer

and the corresponding outer skin and between the corresponding outer skin and the inner surface of the protective device whose outer surface is intended to be in contact with the support surface.

25. (cancelled).

26. (currently amended) The prosthesis as claimed in claim ~~25~~ 24 wherein the protective device is placed around the body part to protect the body part regardless of the orientation of the body part on the support surface.

27. (currently amended) The prosthesis as claimed in claim ~~25~~ 24 wherein the protective device is comprised of a generally rectangular cushion.

28. (currently amended) The prosthesis as claimed in claim ~~25~~ 24 wherein the protective device is comprised of a generally semi-cylindrical sleeve.

29. (currently amended) The prosthesis as claimed in claim ~~25~~ 24 wherein the protective device is comprised of a generally oblong cushion with a depression located opposite to the bony portion.

30. (currently amended) The prosthesis as claimed in claim ~~25~~ 24 wherein the ~~pad-like structure~~ protective device includes means for attaching the prosthesis to the body part.

31. (currently amended) The prosthesis as claimed in claim ~~25~~ 24 wherein there is included a layer of dressing between the outer skin

layer and the ~~outer~~ inner surface of the ~~pad like structure~~ protective device.

32. (currently amended) The prosthesis as claimed in claim ~~25~~ 24 wherein there is included a layer between the outer skin layer and the outer surface of the pad like structure to allow the skin to breathe.

33. (currently amended) The prosthesis as claimed in claim ~~25~~ 24, wherein the body part to be protected is at least one of the heel, ankle, trochanter, knee, sacrum, coccyx, buttocks, ischium, scapula, elbow and occiput; and wherein the inner surface of the protective device conforms to its respective body part.

34. (currently amended) The prosthesis as claimed in claim ~~25~~ 24 wherein the thickness of the protective device may be selectively increased by adding layers to the outer surface of the protective device for further decreasing the pressure at the interface between the bony portion and its surrounding soft tissue layer.

35. (currently amended) A prosthesis for protecting a part of the human body from developing a pressure ulcer, or for healing an existing pressure ulcer, comprising:

said body part to be protected including a bony portion with a surrounding soft tissue layer between the bony portion and an outer skin layer, and wherein, when the body part is in direct contact with a support surface, the bony portion tends to concentrate the weight of the body part and the bony portion over a relative small area and volume causing there is pressure to be developed at the

interface between the bony portion and the soft tissue layer, across the soft tissue layer, between the soft tissue layer and the outer skin layer and between the outer skin layer and the support surface which is a function of ~~at least one of~~ the weight of the body part [,] divided by the area over which the weight is distributed and the thickness of the soft tissue layer, and wherein when the pressure exceeds a certain critical value ( $P_c$ ), pressure ulcers may develop within the body part;

a protective structure ~~to be applied to~~ enclosing the bony portion of the body part to be protected and located between the bony portion of the body part to be protected and the underlying support surface; said protective structure functioning as an extension of the soft tissue layer surrounding the bony portion and having an inner surface conforming to the body part ~~to which it is applied~~ encloses and having an outer surface suitable for making contact with ~~any arbitrary~~ the support surface; and said protective structure having sufficient thickness and softness to distribute the weight of the body part over an extended area and volume such that the pressure exerted between the bony portion associated with the body part and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding outer skin is less than the critical value of pressure ( $P_c$ ) that would cause a pressure ulcer to develop in that part of the body; and wherein the protective structure is shaped to enclose the region of the body part containing the bony portion to increase the surface

area at the interface between the bony portion and its surrounding soft tissue layer and across the soft tissue layer and between the soft tissue layer and the outer skin layer and between the outer skin layer and the support structure over which the concentrated weight is distributed for decreasing the pressure at the interface between the bony portion and the soft tissue layer surrounding the bony portion and within the soft tissue layer and at the interface between the soft tissue layer and outer skin below the critical value of  $P_c$ .

36. (currently amended) The prosthesis as claimed in claim 35 wherein the critical pressure causing a pressure ulcer is a function of the length of time a given pressure is present, and wherein ~~certain~~ selected properties of the protective structure applied to the body part, including its size, softness and thickness, ~~may be~~ are selected to have different values as a function of the length of time the body part is to ~~lie~~ be on the support surface.

37. (cancelled).

38. (currently amended) The prosthesis as claimed in claim 35, wherein selected properties of the protective structure changes gradually as a function of time to gradually increase the area and volume over which the concentrated weight is distributed in order to ~~provide increasingly reduced~~ gradually reduce the pressure at the interface between the bony portion and the soft tissue layer surrounding the bony portion and within the soft tissue layer and at the interface between the soft tissue layer and outer skin ~~to~~ of the body part to which it is applied.

39. (currently amended) The prosthesis as claimed in claim 35, wherein selective characteristics of the protective structure including at least one of its thickness, softness, area, volume and compression modulus ~~undergoes~~ undergo change as a function of time for increasing the effective surface area and decreasing the pressure applied to the body part components.

40. (currently amended) A protective device for protecting a part of a human body, where the body part includes a bone structure and a soft tissue layer between the bone structure and an outer skin layer intended to rest upon a support surface, comprising:

a ~~pad-like structure~~ to be applied to the body part to be protected, between the body part and the support surface; said ~~pad-like structure~~ having an inner surface conforming to the body part to which it is applied and having an outer surface suitable for making contact with the support surface; and said ~~pad-like structure~~ for distributing the weight of the body part over an extended area and volume in order to reduce the pressure exerted between the bone structure within the body part and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding outer skin layer and between the corresponding outer skin layer, the ~~pad-like structure~~ and the support surface;

wherein the bone structure includes a bony prominence tending to concentrated the weight of the bone structure and overlying body part, defined as W, over a relatively small area, defined as A1, causing a pressure of P1 equal to

W/A1 at the interface between the bony prominence and its underlying soft tissue layer, where the body part is in direct contact with the support surface;

wherein the pad surrounds the region of the body part containing the bony prominence and is located between the body part and the support surface to cause the effective area between the bony prominence and its underlying soft tissue layer to be equal to A2, where A2 is greater than A1, whereby the resulting pressure between the bony prominence and its underlying soft tissue layer is P2 which is equal to W/A2, where P2 is less P1; and the protective device is selected to make P2 have a value below a critical value which would tend to cause ulcers in the body part.

41. (withdrawn) A method for protecting selected body parts from developing pressure ulcers or for healing an existing pressure ulcer comprising the steps of:

ascertaining the body parts of an individual prone to the development of pressure ulcers when the individual is placed on a support surface; and

as to each body part ascertained to be prone to the development of a pressure ulcer applying to each different part a protective device having an inner surface conforming to the body part and having an outer surface suitable for making contact with the support surface for enabling the weight associated with each one of said body parts to be distributed over an extended area and volume.

42. (withdrawn) The method as claimed in claim 41, wherein the step of ascertaining the body parts prone to the development of pressure ulcers includes the step of ascertaining at least one of the following:



the height, weight, skeletal dimensions of the individual, dimension of body part, weight of body part, contour of body part and shape of the body of the individual and the age, gender level of continence, nutritional status, presence of diseases and state of mind of the individual.

43. (withdrawn) The method as claimed in claim 42 wherein body parts of concern include a bony prominence with a soft tissue layer between the bony prominence and the outer skin and wherein the step of ascertaining whether a body part is prone to developing a pressure ulcer includes ascertaining at least one of the following: the thickness of the soft tissue, its behavior in compression, its behavior in shear, its behavior in tension, its behavior in friction, and the moisture level of the outer skin layer.
44. (withdrawn) The method as claimed in claim 41 further including the step of placing the individual on a support surface; and wherein the step of applying a protective device to each different part protects the different body parts regardless of the nature of the support surface.
45. (withdrawn) The method as claimed in claim 44 wherein the step of applying a protective device includes attaching a protective device to a selected body part, each protective device placed between the support surface and the body part to be protected, each protective device having an inner surface conforming to the body part to which it is attached and having an outer surface suitable for making contact

with the support surface; each protective device having sufficient thickness and softness to distribute the weight of the body part over an extended area and volume such that the pressure exerted between the bony portion associated with the body part and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding outer skin and between the corresponding outer skin and the support surface is less than a critical value of pressure ( $P_c$ ) that would cause a pressure ulcer to develop in that part of the body.

46. (withdrawn) The method as claimed in claim 41, wherein applying a protective device to each different body part includes ascertaining the thickness of the soft tissue layer of a selected body part and placing a pad between a selected body part and the support surface such that the pressure developed across the soft tissue layer of the corresponding body part is below a certain level.
47. (withdrawn) The method as claimed in claim 46, wherein a portion of the protective device is formed to have one of the following shapes: rectangular, cylindrical, semi-cylindrical, toroidal, ellipsoid, oblong, triangular and a combination thereof.
48. (withdrawn) The method as claimed in claim 47, wherein said pad is for distributing the weight of the body part over an extended area and volume and for reducing the pressure at the interface between the bony portion and its corresponding soft tissue layer, across the

corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding outer skin and between the corresponding outer skin and a support structure is less than the pressure that would cause a pressure ulcer to develop in that part of the body.

49. (withdrawn) The method as claimed in claim 41 wherein the step of ascertaining various characteristics of an individual to be outfitted with protective devices includes the step of performing at least one of the following: invasively measuring the thickness of the soft tissue layers, non-invasively measuring the thickness of the soft tissue layers, and wherein the step of applying a protective device includes the step of selecting the prosthesis best suited for the person's body part in order to heal an existing pressure ulcer or to prevent the development of one.
50. (withdrawn) The method as claimed in claim 41 wherein the step of ascertaining the thickness of the soft tissue layer includes measuring the thickness of the soft tissue layer using at least one of the following: X-rays, CAT scans, MRIs, ultrasound, any suitable diagnostic tool.
51. (withdrawn) A kit of protective devices for protecting a selected number of different body parts of a person from developing a pressure ulcer or for healing an existing pressure ulcer, where each body part to be protected includes a bony portion with a soft tissue layer between the bony portion and an outer skin layer, and where the body part is to be protected when the body part is in contact with a

support surface and the weight of the body and the body part causes pressure to be developed at the interface between the bony portion and its corresponding soft tissue layer, across the soft tissue layer and between the skin layer and the support surface which may cause a pressure ulcer to develop in the body part, the kit comprising:

a set of different protective devices to be applied to respective body parts to be protected, each protective device having an inner surface conforming to the body part to which it is to be applied and having an outer surface suitable for making contact with the support surface; each protective device for distributing the weight of its corresponding body part over an extended area for reducing the pressure at the interface between its corresponding bony portion and its corresponding soft tissue layer.

52. (withdrawn) The kit of protective devices as claimed in claim 51 including a series of different sized protective devices for the same body part in order to fit persons of different sizes.
53. (withdrawn) The kit of protective devices as claimed in claim 51 including a protective device for at least one of the following body parts: heel, trochanter, ankle, knee, sacrum, coccyx, ischium, scapula, elbow, buttocks and occiput.
54. (withdrawn) The kit of protective devices as claimed in claim 51 including a series of pads of predetermined thickness which can be attached to the outer surface of selected protective devices for increasing the thickness of the protective device applied to a body part.

55. (withdrawn) The kit as claimed in claim 51 wherein the protective devices include a series of protective devices for a particular body part where the thickness of each prosthesis is different to enable the selection of a more optimum protective device for the needs of a particular person.
56. (withdrawn) The kit as claimed in claim 51 including a series of protective devices for the same body part having different degrees of softness for enabling the selection of a more optimum protective device to meet the needs of a particular person.
57. (withdrawn) The kit as claimed in claim 51 further including wound dressing to provide pressure relief and wound care within the same protective unit.
58. (withdrawn) The kit as claimed in claim 51 further including means for shaping selected protective devices for enabling more precise fitting of the device to the body of a person where better contact is required.
59. (withdrawn) The kit as claimed in claim 51 further including means for adding layers to the inner surface of selected protective devices for protecting the outer skin of the person fitted with a protective device.
60. (withdrawn) The kit as claimed in claim 51, wherein each protective device includes at least one of the following:
- a. a dressing;
  - b. a medicated dressing
  - c. a hydrocolloid dressing;

- d. a hydrocolloid dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- e. a hydrogel;
- f. a hydrogel dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- g. a thin film dressing;
- h. a thin film dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- i. a gauze dressing;
- j. a gauze dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- k. a non woven-dressing;
- l. a non woven-dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- m. a foam dressing;
- n. a foam dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;

- o. a material adapted to absorb any excess moisture and drainage;
- p. a material which exhibits moisture vapor permeability; and
- q. a material which exhibits permeability to air for enabling air circulation;
- r. a material containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance; and
- s. material including therapeutic components such as growth factors and wound healing accelerators.

61. (withdrawn) A garment adapted to protect a selected number of different body parts of a person, where each body part to be protected includes a bony portion with a soft tissue layer between the bony portion and an outer skin layer, and where the body part is to be protected when the body part is in contact with a support surface and the weight of the body and the body part causes pressure to be developed at the interface between the bony portion and its corresponding soft tissue layer, across the soft tissue layer and between the skin layer and the support surface which may cause a pressure ulcer to develop in the body part, the garment comprising a selected number of sections corresponding to said selected number of body parts to be protected; each one of said sections for securing a protective device at a location corresponding to the location of the body part to be protected; and each protective device having an inner surface conforming to the body part to which it is to be applied and having an outer

surface suitable for making contact with the support surface; each protective device for distributing the weight of its corresponding body part over an extended area for reducing the pressure at the interface between its corresponding bony portion and its corresponding soft tissue layer.

62. (withdrawn) The item of attire as claimed in claim 61, wherein the protective devices are secured to the body of the person regardless of movement of the person.

63. (withdrawn) The item of attire as claimed in claim 62, wherein the sections of the item of attire includes flaps for enabling the selective insertion and removal of protective devices.

64. (withdrawn) The item of attire as claimed in claim 61 for securing selected protective devices to selected body parts regardless of the orientation of the body of the person and for providing protection to the selected body parts regardless of the characteristics of the support surface.

65. (withdrawn) A system for protecting a selected number of different body parts of a person, where each body part to be protected includes a bony portion with a soft tissue layer between the bony portion and an outer skin layer, and where the body part is to be protected when the body part is in contact with a support surface and the weight of the body and the body part causes pressure to be developed at the interface between the bony portion and its corresponding soft tissue layer, across the soft tissue layer and between the skin layer and the support surface which may cause a pressure ulcer to develop in the body part;



means for applying a protective device to selected ones of the body parts to be protected; each such protective device having an inner surface conforming to the body part to which it is to be applied and having an outer surface suitable for making contact with the support surface; each protective device for distributing the weight of its corresponding body part over an extended area for reducing the pressure at the interface between its corresponding bony portion and its corresponding soft tissue layer; and a garment to be placed over at least one body part, said garment having sections located at sites corresponding to the locations of the body part to be protected and said garment adapted to be placed over, at least, a portion of the body of the person for securing at least one protective device to the body part to be protected.

66. (withdrawn) The system as claimed in claim 65 for securing selected protective devices to selected body parts regardless of the orientation of the body of the person and for providing protection to the selected body parts regardless of the characteristics of the support surface.

67. (currently amended) A prosthesis for healing a preexisting pressure ulcer or protecting a body part from developing a pressure ulcer, where the body part includes a bone with a bony prominence, where the bony prominence tends to concentrate the weight of the body part over a small region whereby there is substantial pressure developed at the interface between the bony prominence and the soft tissue layer, includes ~~the implanting of a pad-like~~ bone to soft tissue interface pressure reducing structure implanted at the site of the bony prominence which ~~pad-like~~ pressure reducing structure functions to increase the

contact area of between the bony prominence ~~with~~ and the ~~overlying~~ surrounding soft tissue and thereby causes the weight borne by due to the body part and the bony prominence to be distributed over a larger contact area with the soft tissue and to thereby decrease the pressure to which the soft tissue is exposed.

68. (currently amended) The prosthesis as claimed in claim 67, wherein the ~~pad-like~~ bone to soft tissue interface pressure reducing structure is a pad inserted between the bony prominence and its surrounding soft tissue layer and which is fabricated from a material of similar or greater firmness to that of the bony prominence and which behaves in a similar manner to the bony prominence.

69. (currently amended) The prosthesis as claimed in claim 67, wherein the ~~pad-like~~ bone to soft tissue interface pressure reducing structure is fabricated from a material of similar or less firmness to that of the soft tissue and which behaves in a similar manner to the soft tissue layer in diffusing the weight between the bony prominence and the actual soft tissue layer.

70. (currently amended) The prosthesis as claimed in claim 67, wherein the ~~pad-like~~ bone to soft tissue interface pressure reducing structure is a pad fabricated from a material having a firmness varying from that of the bony prominence to that of the soft tissue and to a firmness softer than that of soft tissue.

71. (currently amended) The prosthesis as claimed in claim 67, wherein the ~~pad-like~~ bone to soft tissue interface pressure reducing structure is a pad fabricated from a material enabling the growth of at least one of new bone,

new cartilage and new soft tissue in the region between the original bony prominence and the original soft tissue layer.

72. (currently amended) The prosthesis as claimed in claim 70, wherein the pad material includes substances which serve as a matrix and seeding structure for the formation of new bone or new soft tissue or any suitable new matter.

73. (currently amended) The prosthesis as claimed in claim 67, wherein the ~~pad-like~~ bone to soft tissue interface pressure reducing structure is a pad formed of a fatty like substance which exhibits little, if any, dimensional change as a function of time.

74. (original) The prosthesis as claimed in claim 73, wherein the fatty substance may be one of silicone and wax which exhibit little dimensional change as a function of time.

75. (currently amended) The prosthesis as claimed in claim 67 wherein the ~~pad-like~~ bone to soft tissue interface pressure reducing structure is a pad formed of material having a first volume when first implanted and which expands to a predetermined size after implantation.

76. (currently amended) The prosthesis as claimed in claim 67 wherein the ~~pad-like~~ bone to soft tissue interface pressure reducing structure is made of a material which dissolves over time.

77. (currently amended) A protective device for protecting a part of a human body ~~from~~ from developing a pressure ulcer or for healing an existing pressure ulcer, where the body part includes a bone structure with a bony

prominence tending to concentrate the weight of the body part over a small region and a soft tissue layer between the bony prominence of the bone structure and an outer skin layer intended to be in contact with a support structure such that there is an undesirable high pressure at the interface between the bony prominence of the bone structure and the soft tissue layer, across the soft tissue and outer skin layers and at the interface between the outer skin layer and the support structure, when the body part is directly situated on the support structure, the protective device comprising:

a hard shell-like structure of limited size to be applied to the area of the body part containing the bony prominence ~~be protected~~; said hard shell-like structure having an inner surface conforming to the body part to which it is applied and having an outer surface suitable for making contact with the support structure; said shell -like structure for distributing the weight of the body part over an extended area and volume such that the pressure exerted at the interface between the bony prominence of the bone structure and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding outer skin layer and between the corresponding outer skin layer and a support structure is less than the pressure that would cause a pressure ulcer to develop in that part of the body; and wherein the shell-like structure is shaped to reduce the pressure developed at the interface between the bony prominence and its

corresponding soft tissue layer below a predetermined level and is of limited size to enable the protected body part to move freely in all directions which the body part can move in the absence of the protective shell-like structure.

78. (cancelled)

79. (currently amended) A protective device as claimed in claim ~~78~~ 77, wherein the body part to be protected is at least one of the heel, trochanter, knee, sacrum, coccyx, ischium, scapula, elbow, ankle, buttocks and occiput; and wherein the inner surface of the shell-like structure conforms to its respective body part.

80. (original) A protective device as claimed in claim 79, wherein the inner surface of the shell-like structure includes a soft inner liner.

81. (original) A protective device as claimed in claim 79, wherein the outer surface of the shell like structure is covered with a soft material to prevent damaging or pressuring any other body parts.

82. (original) The protective device as claimed in claim 79 wherein the hard shell like structure is shaped to contour the body part to be protected and reduce pressure on the body part without immobilizing the body part.

83. (withdrawn) A protective device for protecting a part of a human body from developing an ulcer or for healing an existing pressure ulcer, where the body part includes a bone structure and a soft tissue layer between the bone structure and an outer skin layer intended to be in contact with a support structure, comprising:

a relatively firm mold to be applied to the body part to be protected; said relatively firm mold having an inner surface conforming generally to the body part to which it is applied and having an outer surface suitable for making contact with the support structure;

applying an expandable material between the outer skin of the body part to be protected and the inner surface of its corresponding relatively firm mold, said expandable material expanding as a function of the absorption of fluid as a function of time.

84. (withdrawn) The protective device as claimed in claim 83, wherein the expandable material may include at least one of the following:

- (a) gel formers including at least one of calcium alginate, gelatin and cross-linked polyethylene oxide;
- (b) gum formers including at least one of carboxymethylcellulose, methylcellulose and guar gum;
- (c) compressed fibrous absorbents, such as cardboard; and
- (d) compressed foam materials such as hydrophilic polyurethane foam.

85. (withdrawn) A method for protecting a part of a human body, where the body part includes a bone structure and a soft tissue layer between the bone structure and an outer skin layer intended to be in contact with a support structure such that there is pressure at the interface between the bone structure and the soft tissue layer, across the soft tissue and outer skin layers and at the interface between the outer skin layer and the support structure, the method comprising the step of:

applying an expandable material to the outer skin of the body part to be protected, said expandable material expanding as a function of the absorption of fluid as a function of time.

86. (withdrawn) The method as claimed in claim 85 wherein the body part to be protected is at least one of the heel, trochanter, knee, sacrum, coccyx, ischium, scapula, elbow, ankle, buttocks and occiput; and wherein the expandable material may includes at least one of the following:

- (a) gel formers including at least one of calcium alginate, gelatin and cross-linked polyethylene oxide;
- (b) gum formers including at least one of carboxymethylcellulose, methylcellulose and guar gum;
- (c) compressed fibrous absorbents, such as cardboard; and
- (d) compressed foam materials such as hydrophilic polyurethane foam.

87. (currently amended) A protective device for protecting a part of a human body, where the body part includes a bone structure of the type which has undergone amputation and requires a support surface and a soft tissue layer surrounding the bone structure and wherein, when the body part is in contact with a support surface designed to support the bone structure, there is pressure at the interface between the bony portion and the soft tissue layer, across the soft tissue layer, between the soft tissue layer and the outer skin layer and between the outer skin layer and the support surface, comprising:

a pad-like structure to be applied to the body part to be protected and to be placed between the bone structure and the support surface; said pad-like

structure having an inner surface conforming to the body part to which it is applied and having an outer surface suitable for making contact with the support structure; and said pad-like structure having sufficient thickness and softness to distribute the weight of the body part over an extended and increased area and volume such that the pressure exerted against the soft tissue layer is decreased and is less than the pressure that would cause a pressure ulcer to develop in that part of the body.

88. (original) The protective device as claimed in claim 87, wherein the body part to be protected is a body part which has been amputated, and wherein the support structure is a prosthesis, and wherein the pad-like structure is placed between the amputated portion of the body part and the prosthesis.

89. (original) The protective device as claimed in claim 88, wherein the pad-like structure is formed of a soft material.

90. (original) The protective device as claimed in claim 88, wherein the pad-like structure is formed of a hard material.